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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/413,785      | 10/07/1999  | STAVROS C. MANOLAGAS | D6156               | 2424             |

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ATLANTA, GA 30303-1763

EXAMINER

FALK, ANNE MARIE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/413,785

Applicant(s)

MANOLAGAS ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 2/24/03 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 3, 4 and 15.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Anne-Marie Falk, Ph.D.  
Primary Examiner  
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Applicants' arguments have been fully considered, but are not deemed persuasive. Applicants' arguments are not unlike those presented earlier.

At page 2, paragraph 3 of the response, Applicants argue that the pending claims are limited to the use of parathyroid hormone to prevent bone loss or stimulate bone formation in a host that is being treated with one or more glucocorticoid compounds or experiencing adverse bone effects resulting from contact with one or more glucocorticoid compounds, representing patients that are experiencing glucocorticoid-induced bone loss.

At page 3, paragraph 2 of the response, Applicants further argue that osteoporosis is classified into two major categories: primary and secondary. Applicants assert that it has generally been found that treatment of secondary osteoporosis is more complex than treatment of primary osteoporosis and it is largely dependent on the underlying disease. No support is offered for this assertion. Moreover, Applicants have not pointed to any reason why one of skill in the art would not recognize, based on the disclosures of Lane et al. and Finkelstein et al., that PTH administration could be used in any situation that results in bone loss or otherwise necessitates stimulation of bone formation, including patients experiencing adverse bone effects as a result of contact with a glucocorticoid. One of skill in the art would have anticipated a reasonable expectation of success in using the methods of Lane et al. and Finkelstein et al. in other situations, i.e. to treat osteoporosis induced by factors other than estrogen deficiency, because there is nothing in their disclosures to suggest that the method would not work in other situations where stimulation of bone formation is desired.

At page 3, paragraph 3 of the response, Applicants assert that the claims are limited to treatment of one type of secondary osteoporosis – glucocorticoid-induced osteoporosis. Applicants argue that their discovery that PTH can be used to reduce the adverse effects of glucocorticoids on bone was surprising and that the teachings of Lane et al. and Finkelstein et al. are directed solely to primary osteoporosis due

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## Continuation Sheet (PTO-303)

to estrogen deficiency. Applicants further argue that there is no suggestion or motivation for one skilled in the art to apply the teachings of Lane and Finkelstein to patients with glucocorticoid-induced osteoporosis because primary and secondary osteoporosis are recognized as separate categories of osteoporosis with different etiologies and clinical manifestations, and therefore one of skill in the art would not find it obvious to apply the teachings of Lane and Finkelstein to a distinct disease state. The Examiner does not agree because there is nothing in Lane et al. or Finkelstein et al. to suggest that PTH-stimulated bone formation is limited to use in estrogen-induced osteoporosis and would not be broadly applicable to stimulating bone formation in other situations where stimulation of bone formation is desired. On the contrary, Finkelstein et al. does discuss other situations where PTH administration can be used to prevent bone loss, specifically the reference teaches that PTH administration prevents castration-induced bone loss and completely reverses established osteopenia (p. 1067, column 3, paragraph 3). Furthermore, Lane et al. states that treatment with intermittent PTH(1-34) "has been shown to significantly increase bone mass in osteoporotic animals and humans" (p. 1470, column 2, paragraph 1). Thus, Lane et al. does not distinguish between primary and secondary osteoporosis, but rather broadly teaches an increase in bone mass in animals with "osteoporosis" in its broadest form, not only estrogen-deficiency-induced osteoporosis.

Claims 3, 4, and 15 remain rejected under 35 U.S.C. 103(a).